Shook, Hardy & Bacon L.L.P.

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BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Pharma Merger Activity Attributed to "Patent Cliff"

Noting that many of the pharmaceutical industry's best-selling products will soon lose their patent protection, industry analysts have reportedly suggested that the potential loss of nearly one-third of industry revenues in the near term could account for recent merger activity among the world's largest pharmaceutical companies. While patent losses affecting 18 of the top 20 prescription drugs will apparently be welcome to consumers and insurers by providing access to cheaper generic versions, the industry is bracing for "the sharpest revenue decline in history." The industry is cutting costs by reducing staff, but is also diversifying product lines, expanding into new geographic markets and investing more in research.

The so-called "patent cliff" may just be part of the "cyclic nature of science," according to some observers, pointing to periodic scientific breakthroughs that lead to new drugs. One pharmaceutical-research firm operator was quoted as saying, "The paradigm of medicinal chemistry that pharmacology has been operating on for 40 to 50 years has been pretty well exhausted. The low-hanging fruit has been picked." *See The Philadelphia Inquirer*, November 12, 2010.

NEW BIOBUSINESS VENTURES

Fibrocell Science Announces Joint Venture with Hefei Meifu Bio-Tech Ltd.

Fibrocell Science, Inc. has announced a joint-venture agreement with Hefei Meifu Bio-Tech Ltd. Co. (Meifu) to develop and market autologous fibroblast therapies for aesthetic, medical and scientific applications in Asia, excluding Japan. Fibrocell Science Asia Co. Ltd. will reportedly allow Fibrocell access to a large and growing aesthetic-application market in Asia.

The agreement calls for Pennsylvania-based Fibrocell, a biotechnology company that focuses on advancing the scientific, medical and commercial potential of autologous skin and tissue, to provide access to its intellectual

property, clinical data and manufacturing processes. Meifu will provide construction and operational costs for a manufacturing facility in Hefei, China, in addition to ongoing operational, research and development expenses.

"In Asia, the health and beauty markets are expanding rapidly, which we believe offer significant opportunity for autologous cellular therapy as a natural and personalized product," Zhou Tao, the joint venture's chair, said in a statement. Meifu develops, manufactures and distributes pharmaceutical anticancer intermediates, generic drugs, dietary supplements, and medical devices for beauty treatments. *See Fibrocell Science News Release*, November 3, 2010.

Joint Venture to Produce Microalgae-Based Food Ingredients

California-based Solazyme, Inc. and France-based Roquette Frères have announced a joint venture to produce and market microalgae-derived food ingredients "subject to regulatory approvals and notifications." Solazyme-Roquette Nutritionals, operational by early 2011, will "launch an entirely new category of natural, healthy and functional ingredients based on microalgae that provide superior nutritional properties along with outstanding taste and texture," according to a press release issued by both companies. Solazyme focuses on renewable oil and bioproducts, and Roquette is a global provider of starch and starch derivatives.

The firms, which have developed microalgal nutritional platforms independently, plan to jointly fund and build a "commercial-scale manufacturing plant with capacity in the tens of thousands of tons of annual production" in an existing Roquette "corn wet mill." "The merger of Roquette's extensive resources with Solazyme's revolutionary microalgae-derived food ingredient technology, which includes heart-healthy algal flours and oils, will provide solutions that improve both product functionality and nutritional profile in large market food ingredient applications," according to the press release. *See Solazyme-Roquette Press Release*, November 8, 2010.

University of Birmingham, Abingdon Health Create Medical Diagnostics Joint Venture

England's University of Birmingham and Abingdon Health have announced a joint venture to develop and market new diagnostic products for health care and other industries. Bioscience Ventures will focus on developing diagnostic tools for conditions such as cancer and genetic-related diseases, platform technologies for areas including infectious-disease and drug testing, and veterinary applications using intellectual property developed at the university.

SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information on SHB's Biotechnology and Life Sciences capabilities, please contact

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Madeleine McDonough
Pharmaceuticals &
Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

Bioscience Ventures will operate from the university's campus in Edgbaston and through Alta Bioscience, its established trading subsidiary company. According to a university press release, the joint venture will also provide services that include analysis and synthesis of DNA, protein and other biochemicals for pharmaceutical and food-industry clients. "There is a clear opportunity to create a new range of diagnostic products from the University's deep knowledge in this important and growing market," Bioscience Ventures' Executive Chair Chris Hand was quoted as saying. *See University of Birmingham Press Release*, November 8, 2010.

INVESTOR NEWS

Biotech Grants Totaling $1 Billion Awarded to Almost 3,000 Companies

The U.S. Qualifying Therapeutic Discovery Project Program has recently identified the biotech companies that will receive part of $1 billion in tax credits or grants under the Affordable Care Act to stimulate research and development. But with almost 3,000 companies awarded the funding, many firms have reportedly received smaller allotments than requested.

RegeneRx of Rockville, Maryland, for example, apparently sought the highest amount that could be allotted—$5 million—for therapies to repair tissue and organ damage, but received approximately $733,000. Although pleased to get the money, the company's president and chief executive told a news source that the company is "obviously somewhat disappointed that we didn't get the full amount we were eligible for because the program was so oversubscribed."

According to the U.S. Department of Health and Human Services (HHS), which announced the award winners in conjunction with the National Institutes of Health (NIH) and the U.S. Department of the Treasury, 4,606 applications were received. Of those, 2,923 biotechnology and medical research companies in 47 states and the District of Columbia were awarded funding, which was available to firms with fewer than 250 employees. "It was an indication of the great opportunity and interest that there were so many applications received," NIH Director Francis Collins said. "Of course, with a $1 billion total amount of money available and with so many applicants being judged as entirely appropriate for this program, it was not possible to make awards as large as $5 million."

The program, designed to help create and sustain new jobs and increase U.S. competitiveness, targets projects that show "significant potential to produce new therapies, address unmet medical needs, reduce the long-term growth of health care costs, or advance the goal of curing cancer within the next 30 years," according to HHS. *See HHS News Release*, November 3, 2010; *The Washington Post*, November 8, 2010.

West Coast Biotech Pioneer Launches Sonoma Biotech Incubator

Howard Leonhardt, who has earned millions from a medical technology invention that repairs aortic aneurysms, has reportedly partnered with the University of Northern California at Santa Rosa to open test labs and clean room facilities to early-stage biotech companies for as little as $500 a month. The incubator program, intended to assist medical technology startups, would also apparently provide entrepreneurial coaching and assistance finding capital. The goal will be to make Sonoma County a center for medical technology. According to Leonhardt, demand for this technology is growing as the world's population ages, and "[t]his market will double in five years." *See The Press Democrat*, November 9, 2010.

BUSINESS CLIMATE

Eleanor Herriman, "Get Ready to Enter the Next Global Biotechnology Market . . . China," *Life Sciences Law & Industry Report*, November 5, 2010

This article makes the case for a prediction that China, already on track to become the third largest pharmaceutical market in the world by 2011, to become a biotech powerhouse that will be open to foreign entry. The Chinese government apparently covers the costs for medicines on a "National Essential Medicines List," and has focused on spurring growth in the biopharmaceutical industry. Its 2009 health care reform program includes a variety of financial incentives, such as tax breaks, support services and incubator space, for both foreign and domestic investors and companies. China's 11th Five Year Plan, covering the years 2006-2010, had biotechnology development as a priority component, and it is anticipated that the 12th Five Year Plan will contain a similar commitment.

With low labor costs and a large pool of well-educated scientists and medical professionals, China's domestic pharmaceutical industry has reportedly grown 20.1 percent from 2005 to 2009. According to this article, with these elements in place, as well as a shift in the population's disease burden from the communicable diseases that are a hallmark of the Third World to those of a developed country, characterized by diseases such as diabetes, hypertension, cancer, and depressive disorders, "big pharma and biopharma have been descending on China as if in a gold rush." More than 700 biotech companies, including 23 percent foreign-invested businesses, were operating in China in 2009. Biotech sales have apparently risen 30 percent annually.

The article concludes, "All the pieces are in place to grow and then sustain a thriving biotechnology industry in China for decades to come. . . . Taken together, the confluence of economic, political, demographic, industrial, and social forces in China have constructed a dynamic biopharmaceutical

industry. While the time has already passed for early entry into the pharmaceutical side of the industry, the novel biologics market is in a very early phase, and hence ripe for new U.S. entrants to execute Chinese strategies."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Stakeholders Provide Input on FDA Review Standards for Biosimilars

The Food and Drug Administration (FDA) recently conducted a two-day hearing to begin the process of determining how it will go about creating review standards for the generic copies (biosimilars) of prescription drugs developed from biological materials (biologics). The health care reform legislation signed into law by President Barack Obama (D) directed FDA to establish a biosimilar approval process while also creating 12 years of patent exclusivity for original biologics. The agency will accept additional public comments until December 31, 2010.

According to news sources, stakeholder viewpoints generally divided along cost, safety and ethics lines. Those companies and industries already in the generics market supported the least amount of clinical support for biosimilar safety and efficacy; they favored extrapolating the safety and efficacy data of a given biologic from one indication to another. Brand-name companies, with patent protection for original drugs and the capacity to produce their own generics, called for more extensive testing. They reportedly contended that extrapolation could present risks and that new clinical trials would be required to assess whether a biosimilar would have the same effect across varying diseases and patient populations.

Those representing the patient perspective apparently expressed concerns over the already high cost of biologics and suggested that a streamlined biosimilar approval process would help those consumers who are cutting their doses in half or avoiding treatment altogether due to skyrocketing costs. Some witnesses were apparently skeptical that an abbreviated review process would make biosimilars less expensive, noting the difficulty in replicating biologics. It was reportedly suggested that drugmakers will likely avoid the biosimilar route to approval and submit an application for a branded biologic to secure 12 years of patent protection and higher prices.

The witnesses also sparred over naming copycat versions of biologics. Pharmacists suggested giving biosimilars unique names, while generic biologic companies called for using the same name to avoid patient confusion.

Some hearing witnesses reportedly discussed the European experience with biosimilars, noting that it established an approval pathway for them in 2005. Europe follows the "similar biological medicinal products" approach, under

which a product will be considered a biosimilar if it demonstrates similarity to a reference innovator biologic, as well as comparable safety and efficacy. According to one witness, about half the biosimilars developed in Europe have had unexpected clinical outcomes in their development, pointing out the need for clinical trials.

Meanwhile, U.S. Senator Bernard Sanders (I-Vt.) submitted a **letter** to FDA Commissioner Margaret Hamburg claiming that the new law on biologics and biosimilars is flawed because it "legislatively mandates that an applicant for marketing approval violate the ethical standards set out in . . . Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects."

According to Sanders, who has thus far been unsuccessful in amending the law, the Helsinki Declaration forbids clinical trials when "conclusive proof of positive and beneficial results" already exists. Sanders contends that the 12-year period of data exclusivity provided by the new law "would prevent an applicant for [FDA] marketing approval of a biosimilar or bioequivalent product from relying on existing data establishing the safety and efficacy of the product." He argues that repeating clinical trials is not only unethical, but a waste of existing taxpayer-funded clinical trial data. *See MedPage Today, Product Liability Law 360*, November 2, 2010; *The* (Delaware) *News Journal*, November 3, 2010; BNA *Life Sciences Law & Industry Report*, November 5, 2010.

EU Legal Services Opinion Could Upset Proposed GM Laws

According to media sources, the EU Council of Ministers' Legal Service has expressed "strong doubts" about the feasibility of a proposal that would allow individual member states to set their own policies for regulating genetically modified (GM) crops. The opinion has reportedly raised questions about whether the legislation would violate World Trade Organization rules, especially since a GM crop ban based on ethical rather than environmental or health concerns would be difficult to uphold in European courts. An EU official has quoted the opinion, which was due to be officially presented on November 11, as saying that, "Economic arguments cannot be relied upon… so the obvious remaining candidate would therefore be ethical reasons."

Also referring to this "leaked" legal opinion, the Institute for Environmental Studies at the VU University Amsterdam has hailed the report as validating the views of its own biotechnology law specialist, Thijs Etty. "This is a sensitive and embarrassing blow for the EU Commission's proposal. As guardian of the Treaty, its primary task is to safeguard the functioning of the EU internal market and to uphold European law. Instead, today's Council's legal service report reveals that the Commission's proposal was grounded on a fundamentally flawed legal basis and impairs the internal market," stated Etty in a

press release. *See Reuters*, November 8, 2010; *IVM Institute for Environmental Studies Press Release*, November 15, 2010.

LITIGATION

Federal Circuit Finds No Limitation on New Evidence in Civil Patent Actions Filed in District Court

A divided en banc Federal Circuit Court of Appeals has determined that patent applicants who are dissatisfied with a Board of Patent Appeals (Board) determination and decide to pursue their claims in federal court under 35 U.S.C. § 145, face no limitations on the right to introduce new evidence other than those pertaining to all civil actions under federal evidentiary and procedural rules. ***Hyatt v. Kappos*, No. 2007-1066 (Fed. Cir., decided November 8, 2010)**. So ruling, the court rejected "the Director's proposal that only 'new evidence that could not reasonably have been provided to the agency in the first instance' is admissible in a § 145 action." Still, the court qualified its ruling by stating that the district court could give less weight to new evidence if its reliability or credibility is in question in light of inconsistent evidence previously introduced during U.S. Patent and Trademark Office (PTO) proceedings.

The issue arose in a case involving a patent application for "a computerized display system for processing image information." The examiner issued 2,546 separate rejections of the applicant's 117 claims, mostly on grounds of lacking support in the specification, failure to comply with the written description and enablement requirements, obviousness, double patenting, or being anticipated. On appeal to the Board, the applicant prevailed on more than 93 percent of the examiner's rejections; he sought reargument, but the Board dismissed the request finding that he raised new arguments that could have been presented earlier to the examiner or the Board.

The applicant then filed a civil action in a D.C. district court under § 145, and the PTO director filed a motion for summary judgment, contending that the pending claims were invalid for failure to comply with the written description requirement. Opposing the motion, the applicant submitted a written declaration indentifying "portions of the specification that one of skill in the art would understand to describe the limitations challenged by the Director." The director countered that the court should not consider the declaration because it had not been previously submitted. The district court agreed, finding that the applicant's declaration was directed to the written description rejections and could have been presented earlier, "certainly by the time his patent application was considered by the Board." The district court then granted the summary judgment motion.

On appeal to the Federal Circuit, a divided panel affirmed, noting that while "it is beyond question that in appropriate circumstances new evidence may be submitted to the district court in a § 145 action," the general practice before the federal courts is "in some circumstances to exclude evidence which a party could and should have introduced before the Patent Office but did not despite an obligation to do so." The panel also apparently concluded that the Administrative Procedure Act imposed restrictions on the admission of new evidence in a § 145 action. The Federal Circuit agreed to rehear the appeal en banc and concluded that the district court applied the wrong legal standard for the admissibility of evidence in a § 145 proceeding and abused its discretion in excluding the declaration.

A concurring and dissenting judge agreed that new evidence may be submitted in a § 145 proceeding, but disagreed with the majority's holding that "when no new evidence is provided, the findings and rulings of the PTO receive the same deferential treatment in the district court as would apply if the cause were not a civil action under section 145, but instead were an Administrative Procedure Act direct appeal to the Federal Circuit under 35 U.S.C. § 141."

Two dissenting judges characterized the en banc majority decision as "a remarkable departure from settled principles of administrative law." According to the dissenting opinion, "Allowing trial de novo in the district court denigrates the important expertise of the PTO, is contrary to established principles of administrative law, finds no support in the language of the statute, and is contrary to decision of at least five other circuits. The majority opinion invites applicants to deliberately withhold evidence from the [U.S. Patent and Trademark Office] in favor of a more hospitable district court forum."

NEWS BYTES

The Manhattan Institute contends that the conflict-of-interest rules in effect at public agencies and research institutions hamper medical progress and cures in a new "**Project FDA Report**."

Upcoming Conferences and Seminars

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Michelle Fujimoto** will join a distinguished panel of speakers addressing biotech industry developments at the **Midyear Meeting** of the International Association of Defense Counsel. Scheduled for February 19-24, 2011, in Pebble Beach, California, this conference features a number of presentations, including the Drug, Device and Biotechnology Committee's program, "The Immediate Future: What Practitioners Need to Know Regarding Developments in the Industry and Their Impact on the Practice of Law." Fujimoto will

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join three other speakers during this program to discuss issues likely to affect the industry over the next five years, including "the increased use of nanotechnology, biopharmaceuticals, and biosimilars," how these developments may affect the business side of the industry and their likely effects on litigation practices.

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Geneva, Switzerland
+41-22-787-2000
London, England
+44-207-332-4500
Washington, D.C.
+1-202-783-8400
San Francisco, California
+1-415-544-1900
Irvine, California
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Kansas City, Missouri
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